

NOV 28 2000

K003361

### SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SDMA 1990 and 21 CFR §807.92

Trade Name: **RENEW® LS-2**  
Common Name: **Tooth shade resin (composite restorative) material**  
Classification  
Name: **Tooth Shade Resin Material, Class II**  
**21 CFR 872.3690**

#### Description of Applicant Device:

RENEW® LS-2 is a packable, low shrink/low stress universal hybrid composite.

#### Intended Uses of Applicant Device:

Intended to be used primarily as a universal (anterior and posterior) dental restorative material to replace missing tooth structure as in:

- 1 Class I and II restorations.
- 2 Core build-ups,
- 3 Class III, IV, and V restorations with a microfill composite, where maximum strength and polishability is desired.

#### Predicate Device:

K 982729 RENEW®

#### Scientific Concepts and Significant Performance Characteristics:

	RENEW® LS-2	RENEW®
INTENDED USE:	Tooth shade resin composite indicated for all types of restorations.	Tooth shade resin composite indicated for all types of restorations.
PRODUCT DESCRIPTION:	<ul style="list-style-type: none"><li>• Universal (anterior and posterior)</li><li>• Light-Cured</li><li>• Hybrid composite</li><li>• Radiopaque</li><li>• Single paste</li></ul>	<ul style="list-style-type: none"><li>• Universal (anterior and posterior)</li><li>• Light-Cured</li><li>• Hybrid composite</li><li>• Radiopaque</li><li>• Single paste</li></ul>
CHEMICAL COMPONENT:	<ul style="list-style-type: none"><li>• Methacrylate resin chemistry with highly filled inorganic glass filler</li><li>• Non-toxic</li></ul>	<ul style="list-style-type: none"><li>• Methacrylate resin chemistry with highly filled inorganic glass filler</li><li>• Non-toxic</li></ul>

**510(k) SUMMARY, continued**

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92

Side-by-side comparisons of RENEW® LS-2 to the predicate device RENEW® clearly demonstrate that the applicant device is substantially equivalent to the legally marketed device.

Comparative bench testing was conducted for RENEW® LS-2 and RENEW®. Review of the testing performed and its results may be found in Section 3, page 9. Based on the results of the bench testing it was concluded that RENEW® LS-2 performs as well as the predicate device, RENEW®, and therefore has proven its safety and efficacy.

Cyndy Oris  
Manager, Regulatory Affairs  
1-800-BIS-DENT or 847-534-6146  
Fax: 847-534-6396

October 24, 2000



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

NOV 28 2000

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Ms. Cyndy Oris  
Manager of Regulatory Affairs  
Bisco, Incorporated  
1100 West Irving Park Road  
Schaumburg, Illinois 60193

Re: K003361  
Trade Name: Renew LS-2  
Regulatory Class: II  
Product Code: EBF  
Dated: October 24, 2000  
Received: October 27, 2000

Dear Ms. Oris:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531

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through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,



FA

Timothy A. Ulatowski  
Director  
Division of Dental, Infection Control  
and General Hospital Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

### Indications for Use

510(k) Number (if known): Not Applicable

Device Name: RENEW® LS-2

#### Indications for Use:

RENEW® LS-2 is a single-paste, packable, low shrink/low stress universal hybrid composite for

1. ☐ Class I and II restorations.
2. ☐ Core Build-ups.
3. ☐ Class III, IV and V restorations with a microfill, where maximum strength and polishability is desired.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ☒ OR Over-the-Counter Use \_\_\_\_\_  
(Per 21 CFR 801.109)

*LS Betz for MS Runner* (Optional Format 1-2-96)  
(Division Sign-Off)  
Division of Dental, Infection Control,  
and General Hospital Devices  
510(k) Number K003361